

## The Outcome of Trabeculectomy Surgery among Patients at University of Gondar Tertiary Eye Care and Training Center, Northwest Ethiopia

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### Abstract

**Objective:** The aim of this study was to assess outcome of Trabeculectomy surgery in terms of preservation of intraocular pressure, visual acuity and optic nerve head defect among patient undergoing trabeculectomy surgery at university of Gondar tertiary eye care and training center.

**Methods:** Hospital based cross sectional study was conducted from January to February 2017. A total of 69 consecutive 'modern' augmented and non-augmented 'safe-technique' trabeculectomies performed over a 2-year period (2012-2014) were assessed. Patients' data from the charts were extracted and analyzed by SPSS version 20. Descriptive statistics were done to summarize the data. Paired samples t-test was performed to compare the correspondent preoperative and postoperative IOP, VA and CDR. P-value<0.05% was considered as statistically significant

**Results:** A total of 69 eyes of 63 patients having post-operative follow up of six months were included in the study. The mean age at the presentation was  $59.12 \pm 12.64$  years. On the last day before surgery, mean snellen VA was  $0.28 (\pm 0.23)$  and it was changed to  $0.24 (\pm 0.20)$   $p=0.38$ , mean IOP was  $31.87 \text{ mmHg} (\pm 10.08)$  and it was reduced to  $18.45 \text{ mmHg} (\pm 6.12)$   $p=0.001$ , mean CDR was  $0.84 \text{ mm} (\pm 0.13)$  and was changed to  $0.85 \text{ mm} (\pm 0.12)$ ,  $p=0.009$  at six months after surgery. Complete success and failure of trabeculectomy was 52 (75.4%) and 8 (11.6%), respectively.

**Conclusion:** Based on IOP, the success rate of trabeculectomy was 75.4%. The mean preoperative VA was dropped by one line at six month after surgery and there was significant reduction of IOP from its base line.

**Keywords:** Trabeculectomy; Gondar city; Ethiopia

**Abbreviations** VA: Visual Acuity; IOP: Intraocular Pressure; CDR: Cup to Disk Ratio

### Introduction

Trabeculectomy is a surgical procedure featuring a partial-thickness scleral flap that creates a fistula between the anterior chamber and the sub-Conjunctival space for filtration of aqueous fluid and the creation of a bleb. It is indicated for the treatment of glaucoma when a maximum tolerated medical therapy is failed to achieve safe intra ocular pressure (IOP) in terms of preservation of optic nerve head and visual field loss [1-3].

Even though trabeculectomy surgery is a gold standard, it has its own complications and possibility of failure in controlling IOP. However, in sub Saharan Africa due to expensive and inadequate hypotensive drugs and trained glaucoma specialists, trabeculectomy is still the most widely performed surgery in treating open angle and chronic angle closure glaucoma [4-6].

The recent advances in trabeculectomy surgery techniques includes sub-tenon anesthesia, careful choice of the surgical site, fashioning of the scleral flap to produce diffuse aqueous flow and better IOP control,

a formed anterior chamber, with outflow control during surgery using an infusion, optimal method of antimetabolites application and using new adjustable sutures. These will reduce the complications like hypotony, infection and scarring which will limit the success of trabeculectomy [7].

From the meta analysis done in Africa regarding the outcome of trabeculectomy surgery, the rate of success varied from 61.8% to 90% in terms of IOP between 10-20 mmHg were reported. Trabeculectomy with or without application of anti-metabolite appears to be a good way of lowering the IOP in Africa [8].

The outcome and the success rate of this surgery were not yet known in Ethiopia; particularly in Gondar city where there is ophthalmology center that has been doing trabeculectomy surgery for more than 10 years duration. Therefore this study will aim to assess the outcome of trabeculectomy surgery in terms of preservation of IOP, Visual acuity (VA) and Optic nerve head defect among patient undergoing trabeculectomy surgery at university of Gondar tertiary eye care and training center, northwest Ethiopia.

## Methods

### Study design and setting

Hospital based cross sectional design study was conducted from January to February 2017 at University of Gondar tertiary eye care and training center. University of Gondar Tertiary eye care and training center is the only tertiary eye care center in northwest Ethiopia, which provides different specialty eye care service and training of ophthalmology, optometry and ophthalmic nurse. It has been serving more than 14 million populations.

### Surgical procedures

All surgeries were done under topical proparacain drops followed by injection of 2 ml of lidocaine without adrenaline that was administered in the superior sub-tenon space at the beginning of dissection for conjunctival flap. After exposing the superior part of globe, fornix based conjunctival flaps were done with posterior dissection. Sterile sponge soaked in 5-fluorouracil 5 mg was applied under the conjunctival flap with rotation of its position for 1 to 3 min depending on the thickness of conjunctiva and tenons. Similarly, mitomycin C (MMC) with concentration of 0.1 mg/ml was used only in 7 eyes as it was not always available. A 3 mm by 4 mm scleral flap was constructed with pre-placement of two 10-0 nylon sutures at the angles. After a temporal paracentesis, a 1 mm sclerostomy was done using Kelly's punch that was followed by peripheral iridectomy. The scleral flap was closed with nylon 10-0 preplaced sutures with suture tension that allowed a slow and continuous trickling of fluid flow under the flap. Additional sutures were added in cases where the flow was robust. The conjunctival flap was closed by purse string sutures at the two ends of the wound and checked for water tightness. Bleb was formed by injecting saline into anterior chamber through paracentesis. At the end of each procedure, sub conjunctival and steroid was given for all injection of a combination of antibiotics patients.

### Outcomes of the study

Trabeculectomy success was defined as IOP <21 mmHg and/or IOP <30% reduction below baseline without any additional medication or bleb needling. Qualified success was if with at least one medication and/or bleb needling, IOP <21 mmHg or IOP <30% reduction below baseline was achieved. Surgical failure was considered if all eyes that were not met the above criteria for success and qualified success.

### Data collection procedures

However, 156 Trabeculectomy surgeries were performed over a 2-year period (2012-2014), only total of 69 eyes of 63 patients data were reviewed due to high percentage of lost follow at 6 months postoperatively. The data was collected from the patients' record charts at a time by trained optometrists using the data extraction format. All patients' record with Trabeculectomy surgery was included in the study. Those who had additional laser therapy and/or tube shunt were excluded from the study. The charts with insufficient data were also excluded. The collected data included: baseline demographic data, preoperative VA, IOP, cup to disc ratio (CDR), duration, types and stages of glaucoma, types of topical and systemic anti glaucomatous medications, intra operative use of anti-metabolites, and post-operative VA, IOP, CDR and the use of anti-glaucomatous medication.

The study was conducted in accordance with the Declaration of Helsinki and approved by the nine members of University of Gondar College of medicine and health science Ethical Review Board.

### Statistical analysis

The secondary data from the charts were carefully coded and entered into EPI INFO 3.5.1 and exported to, processed and analyzed by Statistical Package for the Social Science (SPSS) version 20. Descriptive statistics such as frequency and cross tabulation were done to summarize the data. Paired samples t-test was performed to analyze and compare the correspondent preoperative and postoperative IOP, VA and CDR. P-value <0.05% was considered as statistically significant.

### Results

A total of 69 eyes of 63 patients undergone Trabeculectomy surgery over two years (2012-2014) having postoperative follow up of six months were included in the study. The mean age of patients at the presentation was 59.12±12.64 (Range: 20-86) years. Two third 50 (72.5%) of the subject's sex were male and more than half of them 40 (58%) were living in urban area shown in Table 1.

Variable (n=63)	Frequency	Percentage
<b>Age category</b>		
20-50	15	23.8
51-70	40	63.5
71-86	8	12.7
<b>Sex</b>		
Male	50	72.5
Female	13	27.5
<b>Address</b>		
Urban	37	58.7
Rural	26	41.3

**Table 1:** The socio-demographic characteristics of patients' undergone Trabeculectomy surgery at University of Gondar tertiary eye care and training center, northwest Ethiopia, 2017.

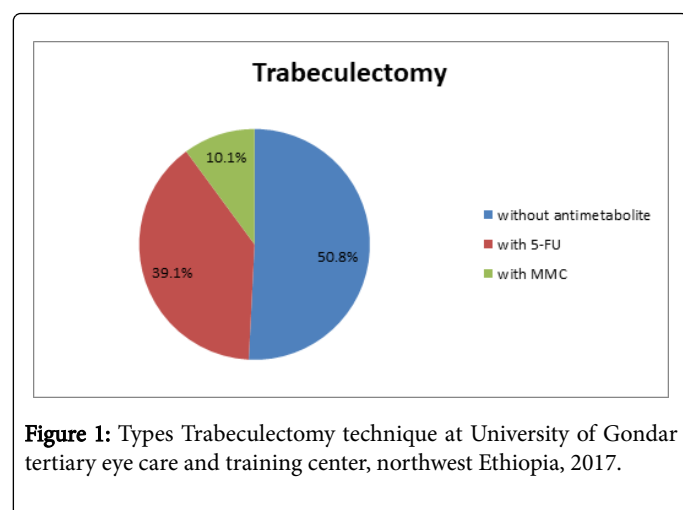
On the presentation day nearly half 33 (47.8%) of all eyes were presented with pseudo-exfoliative glaucoma followed by primary open angle glaucoma 30 (43.5%). Two third 46 (66.7%) of all eyes were on the advanced stages before surgery and all eyes were at least on one ocular hypotensive medication until the surgery day. The mean glaucomatous duration of all eyes before surgery was 5.11 months (SD 7.19) as shown in Table 2.

Variables	Frequency	Percentage
<b>Types of glaucoma</b>		
POAG	30	43.5
PXG	33	47.8
Others	6	8.7

Stages of glaucoma		
Moderate	23	33.3
Advanced	46	66.7
Preoperative duration of glaucoma		
Up to 5 months	47	68.1
>5 months	22	31.9
Types of medication		
Timolol	25	36.2
Timolol and diamox	24	34.8
Timolol and pilocarpine	11	15.9
Timolol, diamox and pilocarpine	9	13

**Table 2:** Clinical status of eyes undergone trabeculectomy surgery at University of Gondar tertiary eye care and training center, northwest Ethiopia, 2017. (POAG: primary open angle glaucoma, PXG: pseudo-exfoliative glaucoma, Others include juvenile open angle glaucoma, Pigmentary glaucoma, and Chronic angle closure glaucoma).

Half of the eyes 35 (50.8%) were undergone Trabeculectomy without anti metabolite whereas in 27 (39.1%) and 7 (10.1%) eyes, 5-Fluorouracil (5FU) and Mitomycin C (MMC) was used respectively as shown in Figure 1.



**Figure 1:** Types Trabeculectomy technique at University of Gondar tertiary eye care and training center, northwest Ethiopia, 2017.

On the last day before surgery, the mean snellen visual acuity of all eyes had been 0.28 ( $\pm$  0.23). At the six months after surgery, it was changed to 0.24 ( $\pm$  0.20)  $p=0.38$ . Mean IOP on the last day before surgery was 31.87 mmHg ( $\pm$  10.08) and it was reduced to 18.45 mmHg ( $\pm$  6.12) with  $p\text{-value}<0.001$ . The mean CDR of all eyes on the last day before surgery was 0.84 mm ( $\pm$  0.13) and was changed to 0.85 mm ( $\pm$  0.12),  $p=0.009$ .

Based on the IOP reduction from preoperative baseline to  $<21$  mmHg and/or 30% reduction, complete success rate of Trabeculectomy was 52 (75.4%). Qualified success was 9 (13%) and failure was 8 (11.6%). The complete success, qualified success and failure of Trabeculectomy among POAG was 22 (31.9%), 4 (44.4%) 4 (50.0%) respectively. The complete success, qualified success and

failure of trabeculectomy in advanced stages of glaucoma was 33 (63.5%), 7 (77.8%) and 6 (75.0%) respectively (Table 3).

Variables	Complete success	Qualified success	Failure
Types of glaucoma			
PAOG	22 (42.3%)	4 (44.4%)	4 (50.0%)
PXG	24 (46.2%)	5 (55.6%)	4 (50.0%)
Others	6 (11.5%)	0	0
Preoperative duration			
Up to 5 months	28 (68.3%)	6 (100%)	5 (71.4%)
>5 months	13 (31.7%)	0	2 (28.6%)
Stages of glaucoma			
Moderate	19 (36.5%)	2 (22.2%)	2 (25%)
Advanced	33 (63.5%)	7 (77.8%)	6 (75%)

**Table 3:** The outcome of Trabeculectomy in terms of types, preoperative duration and stages of glaucoma among eyes undergone the surgery at University of Gondar tertiary eye care and training center, northwest Ethiopia, 2017 (POAG: primary open angle glaucoma, PXG: pseudo-exfoliative glaucoma, Others include juvenile open angle glaucoma, Pigmentary glaucoma, and Chronic angle closure glaucoma).

## Discussion

Different authors defined the success rate based on the different criterion for various post-operative follow up durations. For the eyes in this study, the complete success rate was 52 (75.4%) and qualified success was 9 (13%) at the six months after the surgery. In comparison with two different studies which utilize similar criteria with the present study, this amount of overall success rate in the present study is better [9,10]. However in comparison to three studies with success rates of 88%, 85% and 82%, the current result is lower [11-13]. The Trabeculectomy failure found in this study was 8 (11.6%). The reason for this amount of failure was not clear. But previous studies suggested that pseudophakia, development of an encapsulated bleb (Tenon' cyst), the type and/or length of preoperative medication, higher preoperative intraocular pressures were identified as significant risk factors for the failure of Trabeculectomy [14,15].

In the present study, no significant difference in the outcome of Trabeculectomy between eyes with PXG (46.2%) and POAG (42.3%),  $p=0.34$ . Studies comparing the results of Trabeculectomy between patients with POAG and those with PXF are few in number. The previous study conducted in 1999, which found similar IOP-lowering effect in 30 eyes with PXG and 30 eyes with POAG during a follow-up period of 2 years reported the similar finding with present study [16]. However, the finding from studies published in 2002 and 2013 reported that complete success rates were significantly better in the POAG group than in the PXG group [12,17]. There were no clear reasons why this discrepancy was happens. The incidence of PXG is occur in older ages and had significantly higher preoperative IOP than in POAG might be the reason for lower success rate of Trabeculectomy among PXG eyes. But this study didn't support this finding since in

both group there was no statistically significant difference of Trabeculectomy success rate.

Preoperatively, the mean IOP was  $31.87 \pm 10.08$  mmHg and the mean postoperative IOP at six months after surgery was reduced to  $18.45 \pm 6.12$  mmHg,  $p=0.001$ . This result is similar with different studies conducted by different authors at different time with different follow up period and population [18,19]. It is supported by the result reported by study conducted in Ghana which indicated that there was statistically significant difference between the mean pre-op and post-op IOP ( $p=0.001$ ) at the last examination at six months [20].

The preoperative mean VA was  $0.28 \pm 0.23$  and the mean VA postoperatively at six months was  $0.24 \pm 0.20$ ,  $p=0.038$ . This indicated reduction of post-operative snellen VA by one line from preoperative mean VA. It is in agreement with other studies reports, which show that reduction of VA is a common event usually after long term Trabeculectomy. This might be due the fact that the development or progression of cataract and/or worsening of visual field loss [11].

At the six after surgery, there were a difference in complete and qualified success rates of Trabeculectomy proportion among eyes augmented with 5FU (85.2%, 13%) and MMC (68.6%, 7.4%) and non-augmented trabeculectomies (71.4%, 14.3%) respectively, but the differences were not statistically significant,  $p=0.31$ . However, the study conducted among black West African population, reported that complete" (without medical therapy) postoperative success was greater in the MMC group with a significantly higher proportion achieving an IOP  $<21$  mmHg ( $P=0.02$ ) [6]. The discrepancy observed here might be due to that the present study is a short term while the previous is long term assessment of Trabeculectomy outcome. The baseline, preoperative and postoperative IOP and complications might be makes a difference here.

The mean CDR of all eyes on the last day before surgery was again  $0.84 \pm 0.13$  and was changed to  $0.85 \pm 0.12$  mm ( $p<0.01$ ) at six months after surgery. There was a failure for the CDR $>0.8$  (10.9%). This finding is consistence with study done among East African population, which reported failure on the CDR result from 0.9 or worse and increasing by 0.027 units [21].

The limitation of the present study is that it used secondary data from patient record chart which were not had the information about visual field.

## Conclusion

Based on IOP level the success rate of Trabeculectomy after six months of the surgery was 75.4%, which is satisfactory. The mean preoperative VA was dropped by one line and there was significant improvement of IOP at six months after surgery. To explore predictors for surgical failure and increase the efficacy, it is better to assess long term multicenter prospective follow up study regarding the outcome of Trabeculectomy.

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## Conflict of Authors

All authors declare that there is no conflict of interest.

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